

Appl. No. 09/847,935
Reply to Office Action of May 25, 2004

Remarks

Claims 36, 37, 39-41, 43-50, 53-66, 68, and 70-86 remain pending.

Rejections Under 35 U.S.C. § 102

Claims 59, 78-80, and 83-86 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Garst (U.S. 6,294,563). Claims 78-86 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Gil et al. (U.S. 6,294,553; hereinafter Gil).

Applicant traverses the rejections.

Claim 59 is directed to a composition comprising an adrenergic agonist and an efficacy enhancing component provided in an amount that is effective to form an ion-pair complex with the adrenergic agonist, which remains substantially intact in a high dielectric constant solvent. Claim 78, and the claims dependent therefrom, are directed to a liquid composition comprising a therapeutic component and an efficacy enhancing component provided in an amount effective to form a complex, which is effective to provide a lower or reduced osmotic pressure to the liquid composition relative to a substantially identical composition in which the therapeutic component is not complexed with the efficacy enhancing component.

In rejecting these claims, the Examiner contends that Garst discloses a composition that comprises brimonidine and prostaglandin, and that no amounts and/or conditions are recited

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in the instant claims that would allow the composition to form a complex and exclude the compositions of the prior art from forming a complex.

Applicant respectfully disagrees. The present claims specifically state that the efficacy enhancing component is provided in an amount effective to form an ion-pair complex (claim 59) or in an amount effective to form a complex, which complex is effective to provide a lower or reduced osmotic pressure to the liquid composition relative to a substantially identical composition in which the therapeutic component is not complexed with the efficacy enhancing component (claim 78).

Applicant submits that not all amounts of an efficacy enhancing component are sufficient or effective to form an ion-pair complex with a therapeutic component, or to form a complex, which is effective to provide a reduced osmotic pressure to a liquid composition. The present claims are directed to compositions comprising amounts of an efficacy enhancing component that are effective to form these types of complexes. Limiting the claims to only certain numerical amounts of efficacy enhancing components would unduly restrict the scope of the claims and the scope of patent protection to which applicant is entitled.

The Examiner also states that Gil discloses a composition comprising brimonidine and oleic acid, and that nothing in applicant's composition indicates that a complex would not form in certain embodiments of the composition of Gil. However, with respect, applicant is not required to make such a showing in order to sustain a *prima facie* case of patentability.

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"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (Emphasis added; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

Since Garst does not specifically teach or suggest formation of ion-pair complexes, as recited in claim 59, or complexes, as recited in claim 78, applicant submits that Garst does not specifically teach, or even suggest compositions that comprise an efficacy enhancing component provided in the amounts recited in the present claims. Similarly, since Gil does not specifically teach or suggest the complexes recited in claim 78, Gil does not specifically teach, or even suggest compositions that comprise an efficacy enhancing component in an amount as recited in claim 78. While aspects of Garst and Gil may encompass aspects of the present invention, these references do not teach each and every limitation recited in the present claims. For this reason, applicant submits that the present claims are not anticipated by Garst or Gil.

To the extent the Examiner maintains the rejections, applicant requests the Examiner to specifically identify where Garst and Gil expressly or inherently disclose the claimed compositions, or to provide other evidence in the prior art to support the Examiner's opinions that the complexes of the present claims would necessarily be formed in the prior art compositions. Pursuant to 37 C.F.R. § 1.104(d)(2), applicant respectfully requests the Examiner to provide a reference with support from an affidavit showing that ion-pair complexes, or

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complexes as recited in claim 78, necessarily form when mixing pharmaceutical components. Absent such a showing, applicant submits that the present rejections cannot be maintained, and must be withdrawn.

In view of the above, applicant submits that the present claims, in particular claims 59 and 78-86 are not anticipated by Garst or Gil under 35 U.S.C. § 102.

Rejections under 35 U.S.C. § 103

Claims 36, 37, 39-41, 43, 44, 47-50, 53-58, 70-75, and 77 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Garst. Claims 60-66, 68, 72, 73, and 76 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Gil. Claims 36, 45, and 46 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Shashoua et al. (U.S. Patent No. 5,795,909; hereinafter Shashoua).

Applicant respectfully disagrees with the rejections, and traverses the rejections.

For example, applicant submits that pursuant to 35 U.S.C. § 103(c), Garst and Gil, alone or in any combination, cannot be used to reject the present claims under 35 U.S.C. § 103.

Under 35 U.S.C. § 103(c),

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability

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under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Statement Concerning Common Ownership

Applicant submits that the subject matters disclosed by Garst and Gil, and the instantly claimed invention of the above-identified application were, at the time the presently claimed invention was made, subject to an obligation of assignment to Allergan Sales, Inc..

Because the subject matters disclosed by Garst and Gil, and the presently claimed invention were effectively commonly owned by the same entity at the time of the invention, and since the Examiner relies on Garst and Gil under 35 U.S.C. § 102(e), Garst and Gil cannot be used to preclude patentability under 35 U.S.C. § 103.

Accordingly, because Garst and Gil cannot be used to preclude patentability of the claims pursuant to 35 U.S.C. § 103(c), applicant respectfully submits that the rejections must be withdrawn.

Regarding the rejections of claims 36, 45, and 46 over Shashoua, applicant traverses the rejection.

As a preliminary matter, applicant respectfully disagrees with several statements made by the Examiner. The Examiner states that the generic claim (claim 36) is directed to a composition that comprises alpha-2-adrenergic agonist as a

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therapeutic agent and greater than 0.2% to less than about 10% efficacy enhancing component, and that the rest of the claim bears no patentable weight to the claimed invention.

Applicant disagrees. In determining the differences between the prior art and the present claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). Attempting to distill an invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Obviousness cannot be predicated on what is not known at the time an invention is made. *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). Thus, applicant submits that the "rest of the claim" (claim 36) does bear patentable weight, and must be considered when properly examining the claim "as a whole" under 35 U.S.C. § 103.

In addition, the Examiner states that since Shashoua is silent on the amount of the efficacy enhancing component, it would appear that all or certain amounts of the efficacy enhancing component would be suitable to provide the desired effect and it is within the purview of the person of skill to determine the workable amount of the efficacy enhancing component. The Examiner states that the burden is on applicant to demonstrate such is the case.

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Applicant submits that the burden only shifts to applicant after the Examiner has established a *prima facie* case of obviousness (*In re Rijckaert*, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) citing *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); emphasis ours). In the present situation, applicant submits that the Examiner has not established a *prima facie* case of obviousness, and therefore, the burden remains with the Examiner to show by a preponderance of the evidence that claims 36, 45, and 46 are obvious under 35 U.S.C. § 103 over Shashoua.

With regard to Shashoua, the Examiner's statement that "it would appear that all or certain amounts of the efficacy enhancing component would be suitable to provide the desired effect ..." does not meet the required burden of demonstrating that Shashoua provides a suggestion or a motivation for a person of ordinary skill in the art to choose the specific amounts of the efficacy enhancing component in the claimed compositions, as recited in claim 36.

As the Federal Circuit has again clearly indicated, "[a]lthough a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be clear and particular." (*In re Dembiscak*, 175 F.3d 994, 999 (CAFC) 1999) emphasis ours). Absent such a clear and particular showing, the rejections cannot be properly maintained, and must be withdrawn.

Applicant submits that a *prima facie* case of obviousness has not been established, and that Shashoua does not disclose, teach, or suggest the present invention. For example, Shashoua

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does not disclose, teach, or even suggest a composition, which comprises a therapeutic component comprising an alpha-2-adrenergic agonist, let alone such a composition that also comprises an efficacy enhancing component provided in an amount greater than 0.2% (w/v) and less than about 10% (w/v) and which is present as an ion-pair complex with the therapeutic component, as recited in claim 36.

The Examiner has identified column 20, line 48 of Shashoua as disclosure of a therapeutic component as recited in the present claims. Column 20, line 48 identifies brimonidine tartrate as one of many compounds that may be used in accordance with the invention disclosed therein. More specifically, brimonidine tartrate is identified as one of thousands of potential compounds (e.g., about 8000 compounds).

Applicant submits that Shashoua's listing of one agent among thousands of potential agents provides nothing more than speculation of potential agents that can be provided in a composition, and does not disclose, teach, or provide a suggestion or motivation whatsoever to make obvious, the claimed invention within the meaning of 35 U.S.C. § 103. Applicant submits that based on the teachings of Shashoua, a person of ordinary skill in the art would still be required to guess, test, speculate, and/or arbitrarily "pick and choose" brimonidine tartrate from among the long list of different agents that may be used. Simply put, the brief mention in Shashoua of brimonidine tartrate in a long list of other, different agents, is insufficient for Shashoua to make obvious the presently rejected claims. Therefore, applicant submits

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that Shashoua does not make obvious the presently rejected claims.

In addition, applicant submits that Shashoua does not disclose, teach, or even suggest compositions comprising a therapeutic component and an efficacy enhancing component in the form of an ion pair complex, as recited in claim 36.

Thus, because the Examiner has not established a *prima facie* case, the burden remains with the Examiner to demonstrate that the claimed invention is obvious over Shashoua.

In view of the above, applicant submits that the present claims, in particular claims 36, 45, and 46, are unobvious from and patentable over Shashoua under 35 U.S.C. § 103.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present compositions including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

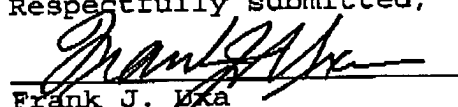
In conclusion, applicant has shown that the present claims are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 36, 37, 39-41, 43-50, 53-66, 68, and 70-86 are allowable, and respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters

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remain unresolved, the Examiner is requested to call (collect)
applicant's attorney at the telephone number given below.

Date: AUGUST 24, 2004

Respectfully submitted,


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